

## REMARKS

### Amendment of Claims

The claims have been amended to recite sterilized compositions with support found at the top of page 7, line 4 in paragraph 25 of the specification.

### Rejections of Claims and Traversal Thereof

In the April 6, 2005 Office Action,

claims 1, 2, 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Drzeniek et al. (Cancer Letters 56; 173-179, 1991); and

claims 1, 2, 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Prall et. (The Journal of Histochemistry and Cytochemistry 44: 35-41, 1996).

These rejections are hereby traversed, and reconsideration of the patentability of herein amended claims is requested, in light of the ensuing remarks.

### Rejections under 35 U.S.C. §102(b)

In the April 6, 2005 Office Action, claims 1, 2, 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Drzeniek or Prall. Applicants respectfully traverse these rejections and submit that the claims are not anticipated by the cited references.

Anticipation under 35 U.S.C. §102 requires the presence, in a single reference, of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). Neither of the cited references meets this standard.

Initially it should be recognized that the presently claimed invention recites a pharmaceutical composition as follows:

1. A **sterilized** pharmaceutical composition for reducing angiogenesis in tumor cells, the method comprising

a monoclonal anti-CD66a antibody which was deposited with DSMZ (German-Type Collection of Microorganisms and Cell Cultures) Braunschweig under DSM ACC2371 on October 22, 1998 and a pharmaceutically compatible carrier, wherein the monoclonal anti-CD66a antibody is in a therapeutically active amount to reduce formation of capillaries in the tumor cells by functionally blocking CD66a on tumor endothelial cell.

Anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). Clearly, none of the cited references provides for a sterilized composition comprising the deposited antibody of the present invention and thus do not anticipate the present invention.

Drzeniek describes the use of the antibody MAb 4D1/C2 in several tissues or solutions and certainly none of these compositions would be considered to be a sterilized composition. The first mention of the use of the MAb 4D1/c2 antibody can be located at page 175, column 1. Specifically, the antibody is combined with rabbit anti-mouse immunoglobulin diluted in 0.1 M carbonate buffer and blocked with BSA/PBS solution. Notably, there is no discussion relating to sterilization. In an assay such as described, sterilization is not a normal procedure because of possible denaturing or damage to the contents. Further in the document, (column 1, page 177) there is a discussion relating to the binding of MAb 4D1/C2 to membrane extracts from the colonic carcinoma cell line HT-29 and again it is highly unlikely that this extract has been sterilized.

Likewise, Prall does not disclose teach or suggest the use of a sterilized compositions as recited in the present invention. As described at page 36, column 1 of Prall, there is a discussion relating to isolation of proteins from granulocytes and normal colon mucosal and then SDS-PAGE was performed in polyacrylamide gel with the protein extracts with the addition of MAb 4D1/C2. No discussion relating to a sterilized solution is provided in this reference. In column 2 of page 36, the MAb 4D1/C2 antibody was mixed with different types of tissues, but again it is highly unlikely that these tissues were sterilized, because sterilization could cause damage to the tissue.

Clearly, neither reference describes the use of a sterilized composition and the Office is not allowed to speculate on such sterilization.

Thus, neither Drzeniek nor Prall "identically disclosed or described" the presently claimed invention as required of an anticipatory reference applied under section 102. (See *In re Felton*, 179 USPQ 295 (CCPA 1973))

Accordingly, applicants respectfully submit that the pending claims are patentably distinguishable over Drzeniek, et al. and Prall, et al. Withdrawal of this rejection under 35 U.S.C. §102(b) is requested.

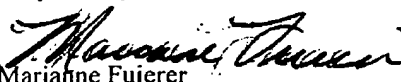
**Fee Payable and Petition for Extension of Time.**

Applicants hereby petitions for a two (2) month extension of time, extending the deadline for responding to the April 6, 2005 Office Action from July 6, 2005 to September 6, 2005. The entry of this petition results in a petition fee of \$225.00. A credit card authorization form in the amount of \$225.00 is included herein for payment of the petition fee. The U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary to the entry of this amendment, and to credit any excess payment, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

**Conclusion**

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Helms reconsider the patentability of pending claims in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Helms is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,

  
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